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Dated: February 24, 2004

Signature:

Karen L. Hudson
(Karen Hudson)

Docket No.: 64230-00003USP1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Lloyd Wolfenbarger, Jr. et al.

Application No.: 10/694,190

Confirmation No.:

Filed: October 28, 2003

Art Unit: N/A

For: A PROCESS FOR DEVITALIZING SOFT-
TISSUE ENGINEERED MEDICAL
IMPLANTS AND DEVITALIZED SOFT-
TISSUE MEDICAL IMPLANTS PRODUCED

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Those patents or publications which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in a prior application number 09/660,422, filed September 12, 2000 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 10-0447, under Order No. 64230-00003USP1. A duplicate copy of this paper is enclosed.

Dated: February 24, 2004

Respectfully submitted,

By


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PTO/SB/08a/b (08-03)

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/694,190
				Filing Date	October 28, 2003
				First Named Inventor	Lloyd Wolfinbarger, Jr.
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	64230-00003USP1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA**	US-4776853	10/1988	Klemet, et al.	
	AB**	US-4801299	01/1989	Brendel, et al.	
	AC**	US-5336616	08/1994	Livesey, et al.	
	AD**	US-5432712	07/1995	Chan	
	AE**	US-5558875	09/1996	Wang	
	AF**	US-5556379	09/1996	Wolfinbarger, Jr.	
	AG**	US-5613982	03/1997	Goldstein	
	AH**	US-5632778	05/1997	Goldstein	
	AI**	US-5820581	10/1998	Wolfinbarger, Jr.	
	AJ**	US-5843181	12/1998	Jaffe, et al.	
	AK**	US-5843180	12/1998	Jaffe, et al.	
	AL**	US-5843182	12/1998	Goldstein	
	AM**	US-5885617	01/1999	Orton	
	AN**	US-5863531	01/1999	Naughton, et al.	
	AO**	US-5855620	01/1999	Bishopric, et al.	
	AP**	US-5899936	05/1999	Goldstein	
	AQ**	US-5916266	06/1999	Yui, et al.	
	AR**	US-5976104	11/1999	Wolfinbarger, Jr.	
	AS**	US-5993844	11/1999	Abraham, et al.	
	AT**	US-5997896	12/1999	Carr, Jr., et al.	
	AU**	US-6024735	02/2000	Wolfinbarger, Jr.	
	AV**	US-6293970	09/2001	Wolfinbarger, Jr.	
	AW**	US-6312474	11/2001	Francis, et al.	
	AX**	US-2001/0049138	12/2001	Dennis, et al.	
	AY**	US-6371992	04/2002	Tanagho, et al.	
	AZ**	US-6376244	04/2002	Atala	
	AA1**	US-6416995	07/2002	Wolfinbarger, Jr.	
	AB1**	US-6432710	08/2002	Boss, Jr., et al.	
	AC1**	US-6428802	08/2002	Atala	
	AD1**	US-6448076	09/2002	Dennis, et al.	
	AE1**	US-6479064	11/2002	Atala	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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Examiner Signature		Date Considered	
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				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	64230-00003USP1

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	CA**	Robert MADDEN, et al., "Decellularized Cadaver Vein Allografts Used for Hemodialysis Access Do Not Cause Allosensitization or Preclude Kidney Transplantation" Journal of Kidney Diseases, Vol. 40, No. 6, December 2002, pages 1240-1243		
	CB**	P.M. DOHMEN, et al., "In Vitro hydrodynamics of a decellularized pulmonary porcine valve, compared with a glutaraldehyde and polyurethane heart valve" Journal of Artificial Organs, Vol. 25, No. 11, 2002, pages 1089-1094		
	CC**	B.S. CONKLIN, et al., "Development and evaluation of a novel decellularized vascular xenograft" Medical Engineering and Physics, vol. 24, 2002, pages 173-183		
	CD**	J. CLARK, et al., "Decellularized Dermal Grafting in Cleft Palate Repair" Facial Plastic Surg., Vol. 5, 2003, pages 40-44		
	CE**	Ronald C. ELKINS, et al., "Decellularized Human Valve Allografts" Society of Thoracic Surgeons, 2001, pages S428-S		
	CF**	Steven GOLDSTEIN, et al., "Transpecies Heart Valve Transplant: Advanced Studies of a Bioengineered Xeno-Autograft" Society of Thoracic Surgeons, 2000, pages 1963-1969		
	CG**	Pascal M. DOHMEN, et al., "Ross Operation with a Tissue-Engineered Heart Valve" Society of Thoracic Surgeons, 2002, pages 1438-1442		
	CH**	David W. COURTMAN, et al., "Biomechanical and ultrastructural comparison of cryopreservation and a novel cellular extraction of porcine aortic valve leaflets" Journal of Biomedical Materials Research, Vol. 29, 1995, pages 1507-1516		
	CI**	Gregory WILSON, et al., "Acellular Matrix Allograft Small Caliber Vascular Prostheses" Trans. Am. Soc. Artif. Intern. Organs, 1990, Vol. XXXVI, pages M340-M343		
	CJ**	David W. COURTMAN, et al., "The Acellular Matrix Vascular Prosthesis: Investigation of its Potential as a Xenograft for Clinical Application" Biomaterial Tissue Interfaces, Vol. 10, 1992, pages 241-246		
	CK**	David W. COURTMAN, et al., "Development of a pericardial acellular matrix biomaterial: Biochemical and mechanical effects of cell extraction" Journal of Biomedical Materials Research, Vol. 28, 1994, pages 655-666		
	CL**	Gregory J. WILSON, et al., "Acellular Matrix: A Biomaterials Approach for Coronary Artery Bypass and Heart Valve Replacement" Society of Thoracic Surgeons, 1995, pages S353-S358		
	CM**	Sotiris A. KORROSSIS, et al., "Tissue Engineering of Cardiac Valve Prostheses II: Biomechanical Characterization of Decellularized Porcine Aortic Heart Valves" Heart Valve Disease, Vol. 11, No. 4, July 2002, pages 463-471		
	CN**	H.H. SIEVERS, et al., "Decellularized pulmonary homograft (SynerGraft) for reconstruction of the right ventricular outflow tract: first clinical experience" Z. Kardiol, Vol. 92, No. 53, 2003		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120.

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Examiner Signature		Date Considered	
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